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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,320	03/08/2001	James Engert	2825.2001-001	1435

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/802,320

Applicant(s)

ENGERT ET AL.

Examin r

Joseph F Murphy

Art Unit

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-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

## Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-17, 19 and 22-24 is/are rejected.
- 7) ☒ Claim(s) 18, 20 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18. 6) ☐ Other:

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## **DETAILED ACTION**

### ***Formal Matters***

Claims 9-12, 14, 17-20 were amended, and new claims 21-24 were added, in Paper No. 19, 2/21/2003. Claims 9-24 are pending and under consideration.

### ***Specification***

The abstract of the disclosure is objected to because it is entitled "Abstract of the Invention". Correction to recite either "Abstract" or "Abstract of the Disclosure" is required. See MPEP § 608.01(b).

### ***Response to Amendment***

The rejection of claims 9-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been obviated by Applicant's amendment and is thus withdrawn.

The rejection of claims 9-20 under 35 U.S.C. 102(b) as being anticipated by Helbecque et al. (1997) has been obviated by Applicant's amendment and is thus withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-17, 19, 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for predicting the likelihood that an individual will have coronary heart disease by determining the nucleotide at position number 11 of SEQ ID NO: 5, wherein the presence of a thymidine is indicative of a greater likelihood of having

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coronary artery disease, or the presence of cytidine is indicative of having a lower likelihood of having coronary artery disease; does not reasonably provide enablement for a method for predicting the likelihood that an individual will have any or all cardiovascular diseases by determining the nucleotide at position number 11 of SEQ ID NO: 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The rejected claims are drawn to a method for predicting the likelihood that an individual will have any or all cardiovascular diseases by determining the nucleotide at position number 11 of SEQ ID NO: 5. The specification demonstrates that the polymorphism at position 11 of SEQ ID NO: 5 is associated with risk of coronary artery disease (page 34, lines 7-11) wherein the presence of a thymidine is indicative of a greater likelihood of having coronary artery disease, or the presence of cytidine is indicative of having a lower likelihood of having coronary artery disease. The Merck Manual sets forth that the term cardiovascular disease encompasses a broad range of diseases, including, *inter alia*, arterial hypertension, orthostatic hypertension, arteriosclerosis, coronary artery disease, heart failure, shock and arrhythmias (see the Merck manual, pages 1599-1601). The diseases encompassed by the term cardiovascular disease have many different etiologies, and some for which the etiology is unknown (compare, e.g. arterial hypertension see page 1630, column 1 and arrhythmias page 1711, column 2). It can be seen from the Merck Manual that while the etiology of arterial hypertension is unknown, the etiology of bradyarrhythmias arise through abnormalities of automatic behavior or conduction through the AV node, while tachyarrhythmias often arise through reentry phenomena.

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Thus, the art teaches that there are many and varied etiologies of cardiovascular diseases, and indeed, some etiologies are unknown. The specification only discloses the correlation of the nucleotide at position 11 of SEQ ID NO: 5 wherein the presence of a thymidine is indicative of a greater likelihood of having coronary artery disease, or the presence of cytidine is indicative of having a lower likelihood of having coronary artery disease. It would require one of skill in the art to determine the nexus between the disclosed polymorphism and all other cardiovascular diseases, since the claims as written encompass any and all cardiovascular diseases. This would require undue experimentation on the part of the skilled artisan, since it would require determining the cause of all cardiovascular diseases, and the correlation between the polymorphism and all cardiovascular diseases.

In addition, the specification does not provide support for a method for predicting the likelihood that an individual will have any or all cardiovascular diseases, including coronary artery disease, by determining the nucleotide at position number 11 of SEQ ID NO: 5, wherein the nucleotide is other than cytidine or thymidine. Since no correlation has been shown between the presence of nucleotides other than cytidine or thymidine at position 11 of SEQ ID NO: 5 and any cardiovascular disease at all, it would require undue experimentation for one of skill in the art to determine the nexus between the presence of a nucleotide other than cytidine or thymidine at position 11 of SEQ ID NO: 5 and the etiology of all cardiovascular diseases, including coronary artery disease, since no nexus has been provided in the specification between the presence of a nucleotide other than cytidine or thymidine at position 11 of SEQ ID NO: 5 and the effect on the risk of developing a cardiovascular disorder, including coronary artery disease. One of skill in the art would need to determine the correlation between the presence of a

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nucleotide at position 11 of SEQ ID NO: 5 other than cytidine or thymidine and the risk of developing all cardiovascular disorders, including coronary artery disease, since the claims as written encompass any and all cardiovascular diseases, correlated to the presence of nucleotides other than cytidine or thymidine. This would require undue experimentation on the part of the skilled artisan, since it would require determining the cause of all cardiovascular diseases, including coronary artery disease, and the correlation between the polymorphism and the diseases.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 24 are vague and indefinite in the recitation of the phrase “cytidine at thymidine position...”. Given the indefinite nature of this phrase, the metes and bounds of the claims cannot be determined.

***Conclusion***

Claims 9-17, 19, 22-24 are rejected.

Claims 18, 20-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.